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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,818	10/30/2003	Jason A. Demers	1062/D72	1303
2101	7590	10/17/2006	EXAMINER	
BROMBERG & SUNSTEIN LLP 125 SUMMER STREET BOSTON, MA 02110-1618			SORKIN, DAVID L	
			ART UNIT	PAPER NUMBER
			1723	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/696,818

**Applicant(s)**

DEMERS ET AL.

**Examiner**

David L. Sorkin

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9-12 and 35-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9-12 and 35-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                                                            |                                                                                         |
|--------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>14 September 2006</u> . | 6) <input type="checkbox"/> Other: _____                                                |

**DETAILED ACTION**

1. The finality of the 28 February 2006 office action is withdrawn.

***Claim Rejections - 35 USC § 112***

2. Claims 9-12 and 35-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The scope of the recitation "determining whether mixing ... can be completed within a predetermined useful lifetime of the first solution" is unclear. It is unclear if determining the useful lifetime is required. It is unclear for what purpose the solution should be useful. No criteria for "useful" are set forth. Also, it is unclear whether that limitations involving "only if" statements are required or optional limitations.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 9-12 and 35-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Section 112, first paragraph requires that applicant's original filing provide enablement for the full scope of each claim. Claims 9 and 45 use the terms "a first solution" and "a predetermined useful lifetime of the first solution". The scopes of these claims include every possible solution and predetermining the "useful lifetime" thereof for every possible use. However, the original filing does not even describe one specific solution and how to predetermine its useful lifetime. No information concerning how to predetermine useful lifetime is provided. For claim 10, enablement of an anti-pathogen solution and the

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predetermination of its useful lifetime are required. Applicant provides no information concerning how to predetermine the useful lifetime of an anti-pathogen compound. In fact, applicant provides only trademarks concerning anti-pathogen compounds rather than a specific description of any such compound.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 9-12 and 35-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Budowsky (US 6,136,586). Regarding claims 9 and 10, Budowsky ('586) discloses a method for combining a first, anti-pathogen substance (ethyleneimine: see col. 21, line 8-40; col. 26, line 36) with a second substance (red blood cell concentrate: see col. 6, line 45; col. 21, line 10; col. 26, lines 49-50; col. 28, line 15) that cannot be mixed directly with the first substance without damaging the second substance, comprising mixing the first substance (ethyleneimine) with a first liquid to produce a first solution, the first solution having a first predetermine concentration of first substance capable of being mixed directly with the second substance without damaging one of the first substance and second substance (see col. 8 line 63 to col. 9 line 61; col. 16 lines 62-67); and mixing the first solution with the second substance (red blood cell concentrate) to produce a second solution having a predetermined concentration of first substance relate to the second substance (see col. 27, line 21 to

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col. 28 line 4). The statement in col. 16, lines 62-67 "Solutions of ethyleneimines were prepared immediately before use..." would have suggested determining if of the first and second solution can be completed within a predetermined useful lifetime of the first solution and mixing the solutions within such a lifetime, to one of ordinary skill in the art.

Regarding claim 11, the first liquid comprises a buffer solution (see col. 9, lines 8-17).

Regarding claim 12, the first liquid is a diluting solution (see col. 16, lines 63-67).

Regarding claims 35-44, the statement in col. 16, lines 62-67 "Solutions of ethyleneimines were prepared immediately before use..." would have suggested determining tionly using the first solution during its useful lifetime since production of the first solution and only mixing it with the second substance if it is still within its useful lifetime. Determining quantity is disclosed in col. 16, line 64. Regarding claims 45-58, these claims are essentially the same as claims 9-12 and 35-44, except for a preamble statement concerning computer control. *In re Venner* 120 USPQ 193, 194 (CCPA 1958) is relied upon for its holding that broadly automatic a manual activity is not sufficient to distinguish over the prior art.

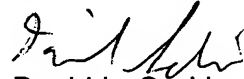
### **Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Sorkin whose telephone number is 571-272-1148. The examiner can normally be reached on 9:00 -5:30 Mon.-Fri..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda L. Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



David L. Sorkin  
Primary Examiner  
Art Unit 1723

DLS